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10/677,947	10/02/2003	Stanton J. Rowe	PVI-S790	9719

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EXAMINER	
PELLEGRINO, BRIAN E	

ART UNIT	PAPER NUMBER
3738	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	**Application No.** 10/677,947	**Applicant(s)** ROWE, STANTON J.	
	Examiner Brian E. Pellegrino	**Art Unit** 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *76,79-83 and 85-99* is/are pending in the application.

4a) Of the above claim(s) *90-92* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *76,79-83,85-89 and 93-99* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the limitation that the "generally continuous stent structure" is "generally free of sharp longitudinal angles along the length of the "generally continuous stent structure" or "generally free of sharp angles" was not found in the specification.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 76,79-81,83,85,86,88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al. (EP 1264582). Park et al. discloses (Fig. 1) a valve prosthesis with support stent structure having a first portion **6** with a first diameter **10** greater than second portion **16** having a second diameter **18**. It can also be seen there is a valve assembly **12** placed in the large diameter section with the outflow end at the inflow end of the stent. Park does disclose the prosthetic device can be modified with various arrangements, paragraph 48. Fig. 2 shows the prosthetic device has a "generally" continuous stent structure despite since the conduit connects the stent structures and is also "generally free" of sharp longitudinal angles along the length of the device. The use of “generally continuous or free” is terminology of relative degree, which has no basis of comparison. For this reason, it is considered broad and relatively unlimited. Thus, it can be construed that there can be some discontinuity of the stent structure and some angle in the structure since there is no defined boundaries by using the term “generally”. It can also be seen the device has a tricuspid configuration, **A1**,**A2**,**A3**. Park additionally discloses the frame material is metal, col. 4, line 12. It can be construed that the frame is expandable since a restraining force (i.e. sheath) is applied to the stent, col. 4, lines 3-5. Park discloses the valve device is formed of what can be construed as leaflets and has slack portions since there is overlap, paragraphs 31-34,39. However, Park et al. fail to disclose the inflow of the valve to be placed in the inflow of the stent support structure. Thus, it would have been an obvious expedient to modify the prosthesis with a reversal of the valve structure with the inlet of the valve toward the inlet of the stent support and the outlet end toward the outlet end of the stent support, since it has been held by the Court of Appeals that a mere reversal of the essential working parts of a previously patented device, does not constitute an improved invention, see MPEP 2144.04. The inflow would just be at the other end and thus the apparatus would be used in a vessel that matches this structural placement.

Claims 82,87,89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al. (EP 1264582) in view of Zakai et al. (2003/153974). Park is explained above. However, Park et al. fail to disclose the valve assembly to be made of pericardial tissue and to stitch the stent to the valve. Zakai et al. additionally discloses the valve is made of pericardial tissue and the stent is made of metal, paragraphs 99,100. It would have been obvious to one of ordinary skill in the art to incorporate stitching to secure the stent to the valve as taught by Zakai et al. with the valve device of Park et al. such that it prevents the valve from moving from the stent and provides a biocompatible material with good compliance.

Claims 93-99 are rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al. (EP 1264582) in view of Schreck (6454799). Park et al. is explained supra. However, Park fails to disclose a continuous rigid support beam extending between the inlet and outlet portion. Schreck teaches (Figs. 2,7) a support beam **42,146** respectively from the inflow end to the outflow end to provide stability to the valve. It would have been obvious to one of ordinary skill in the art to incorporate support structure to the valve device as taught by Schreck in the valved implant of Park such that it strengthens the prosthesis and provides greater stability to the device.

Response to Arguments

Applicant's arguments filed 10/19/07 have been fully considered but they are not persuasive. Applicant argues that Park's device cannot be modified to reverse the working part or valve such that it changes the way fluids can flow through the device. The Examiner is not convinced since by reversing the position of the valve and the placement of the stent device in a patient's vessel it only provides a different use for the valved device, not that it makes the device inoperable. Reversing the valve in Park's device changes the way fluid flow goes through the apparatus and thus it would be used in a different application for example to provide the ability of a large volume of blood from a larger diameter vessel to be delivered to a smaller diameter vessel. It is well known that there are different size blood vessels in the body that carry blood throughout the vascular system and that there are transitions from large capacity vessels to smaller capacity vessels such that a modified version of the Park device can be utilized in these regions of the body. For example a large volume of blood transitions from the ventricle through the aortic valve and into the aorta and thus the device could be used in this application. Fluid flow in the body is not limited from narrow to larger or wider diameter regions. There are applications where fluid flow goes from a larger or wider diameter region to a smaller diameter region and thus provides an alternative use of the apparatus by changing the position of the valve.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M-F (9am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BRIAN E. PELLEGRINO
PRIMARY EXAMINER

Brian E. Pellegrino

TC 3700, AU 3738